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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,601	07/05/2001	Gunter A. Hofmann	GENE1200-10	6087

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EXAMINER
KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,601	Applicant(s) Hofmann et al.
	Examiner Sharon Kennedy	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-57 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In other words, applicant should change "Apparatus" to --Method--.

Double Patenting

3. Claims 1-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,233,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of this application encompass the claims of the '482 patent. It is noted that the relationship between this application and the parent implies that no double patenting rejection since the parent is a divisional of the application to which this claims priority as a continuation. Regardless, an analysis of the claim reveals that this rejection is appropriate.

Claim Rejections - 35 USC § 102

4. Claims 1-5, 7, 15-17, 23-27 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Mir et al., US 5,674,267. Mir discloses the method of increasing the permeability of a cells membrane by applying electric pulses to the cell in order to facilitate the transport of an active agent.

5. Claims 1, 7, 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hofmann, US 5,273,525.

6. Claims 28-31, 34-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hofmann, 5,273,525. Hofmann discloses in the Background of the Invention that it is known that DNA can be delivered directly to the cells of skin tissue, and Hofmann states that the invention is applicable to any tissue. Accordingly, Hofmann disclose the invention for use in skin tissue or at least renders this feature obvious.

Claim Rejections - 35 USC § 103

7. Claims 6, 18-22, 28-34, 42-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mir et al., U.S. 5,674,267. Regarding claims 6 and 33, Mir does not specifically state that the device can be used in vitro or ex vivo, Mir only states that the needles are to be inserted into cancer tissue, assumably in the body. However, it would be obvious to one of ordinary skill in the art to treat the tissue in vitro or ex vivo, for the purpose of experimentation to ensure that the in vivo process is viable. Regarding claims 18-21, 28, 45-48 Mir generically states that the device and method are useful for treating tumors and cancer. It would be obvious to one of ordinary skill in the art to apply the Mir method and device on any specific tumor in the lack of a showing of criticality and in order to widen the range of application for the Mir device. Regarding the needle array of claims 22 and 49, it would be obvious to select any number of needles dependent on the tumor size variable. Regarding the route of administration of the drug,

it would be obvious to one of ordinary skill in the art to deliver the drug by any means, dependent of the comfort of the patient versus the in vivo stability of the drug being administered.

8. Claims 9-14, 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann, US 5,273,525. Hofmann exemplifies that it is well known to deliver sensitive protein therapies to cells using electroporation. It would be obvious to one of ordinary skill in the art to select specific genes or proteins dependent on patient need absent a showing of criticality.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is (703) 305-0154.

January 27, 2003

Sharon Kennedy
Primary Examiner